REMARKS/ARGUMENTS

Status of Application

Claims 1, 8, and 14-29 are pending in this application. Claims 1-3, 6, 8, 9, 12, and 14 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,291,699 to Geddes et al. ("Geddes"). Claims 4, 5, 7, 10, 11, and 13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Geddes.

Applicants have amended independent claims 1, 8, and 4 in a manner that is believed to render the claims patentable over the cited art. Applicants have also canceled dependent claims 2-7 and 9-13, and added dependent claims 15-29.

The Prior Art Rejection and the Claim Amendment

Applicants have amended the independent claims so they all recite, in one way or another, the measurement of an ECG signal, the measurement of a vascular blood pressure, and the directing of therapy if and only if both the ECG signal and the measured vascular blood pressure are indicative of an aberrant heart rhythm.

The claims have been rejected as anticipated or obvious over Geddes, which describes a system that is summarized as follows:

> ... A catheter having a pair of electrodes on the distal portion thereof is insertable into the right ventricle of a heart. A third electrode located on the catheter lies in the superior vena cava. Leads from the pair of electrodes on the catheter communicate with either an implantable defibrillator control unit or an extracorporeal unit containing electrical circuits for sensing electrical R-wave activity, i.e., the electrical signal (ECG) of the ventricles and, upon command, for sensing the existing impedance between the pair of electrodes in the right ventricle thereby sensing mechanical pumping activity. The ECG and impedance circuits generate output voltages which are fed into a logic control circuit that commands the defibrillator to generate a defibrillatory shock when both mechanical and electrical activity sensors indicate the presence of a fibrillatory condition.

Geddes, in the background of the invention section mentions the possibility of using blood pressure as a measurement of cardiac mechanical activity as follows:

> Pressure transducers attached to a catheter introduced into the heart via the superior vena cava have been employed for measuring cardiac mechanical activity, but such transducers have proven susceptible to mechanical failure and to premature disintegration during the high-current levels delivered for defibrillation. It would, therefore, be desirable to employ a single catheter implantable in the right ventricle of a heart by insertion through a superficial vein, or the superior

> vena cava, in the right atrium thereby decreasing surgical risk and trauma to the patient and having a plurality of electrodes for detecting and measuring ECG signals, for detecting and measuring ventricular stroke volume by electrical impedance, and for discharging a defibrillatory shock to the heart.

Applicants have amended the claims to exclude intracardial blood pressure measurement, which is what is mentioned in the above passage. Applicants respectfully submit that Geddes teaches away from the invention as presently claimed.

The Examiner rejected dependent claims 6 and 12 (no longer pending) noting "The fact that Geddes et al. disparage detecting the mechanical activity with such a pressure transducer does not preclude application of the Geddes et al. reference to claim 6 (see MPEP 2131.05)." Applicants respectfully submit that the Examiner cannot rely on MPEP 2131.05. MPEP 2131.05, captioned "Nonanalogous Art," reads as follows:

> "Arguments that the alleged anticipatory prior art is 'nonanalogous art' or 'teaches away from the invention' or is not recognized as solving the problem solved by the claimed invention, [are] not 'germane' to a rejection under section 102." *Twin Disc, Inc. v. United States*, 231 USPQ 417, 424 (Cl. Ct. 1986) (quoting In re Self, 671 F.2d 1344, 213 USPQ 1, 7 (CCPA 1982)). See also *State Contracting & Eng' g Corp. v. Condotte America*, Inc., 346 F.3d 1057, 1068, 68 USPQ2d 1481, 1488 (Fed. Cir. 2003) (The question of whether a reference is analogous art is not relevant to whether that reference anticipates. A reference may be directed to an entirely different problem than the one addressed by the inventor, or may be from an entirely different field of endeavor than that of the claimed invention, yet the reference is still anticipatory if it explicitly or inherently discloses every limitation recited in the claims.).<
>
> A reference is no less anticipatory if, after disclosing the invention, the reference then disparages it. The question whether a reference "teaches away" from the invention is inapplicable to an anticipation analysis. *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 152223 (Fed. Cir. 1998) (The prior art was held to anticipate the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed."). See also *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1948 (Fed. Cir. 1999) (Claimed composition was anticipated by prior art reference that inherently met claim limitation of "sufficient aeration" even though reference taught away from air entrapment or purposeful aeration.).

As can be seen, this section is dealing with anticipation, not obviousness. Since the amended claims are not anticipated by Geddes, MPEP 2131.05 does not apply. Applicants are entitled to take the recognized position that Geddes does not disclose or suggest the invention, and indeed teaches away from it.

Accordingly, independent claims 1, 8, and 14 are allowable. The new dependent claims recite various aspects relating to the measurement of vascular blood pressure, including

the insertion of a pressure transmission catheter, and are allowable at least for the reason that they depend from claims 1 and 8, which are believed allowable.

Claims 18, 19, 27, and 28 recite that the pressure transmission catheter has an outer diameter smaller than about 1.5 mm or that it has an outer diameter in the range of about 0.5 mm - 1.5 mm. This finds support in paragraph **[0023]** of the specification, which discusses the benefits of using a pressure transmission catheter having a diameter of 0.5 mm to 1.5 mm. For example, the size is small enough that the blood vessel wall is likely to seal around the outer diameter of the pressure transmission catheter.

Claims 16 and 17 recite that the pressure transmission catheter is only inserted less than about 10 mm into the vascular lumen or in the range of about 5 mm to 10 mm. The benefits of only inserting the pressure transmission catheter a short way (e.g., about 5 mm to 10 mm) into the blood vessel are also discussed in paragraph **[0023]** of the patent application. For example, inserting a relatively small length of pressure transmission catheter into the blood vessel reduces the likelihood the blood clots will form in the blood vessel. This step also reduces the likelihood that the pressure transmission catheter will damage the endothelial lining of the blood vessel.

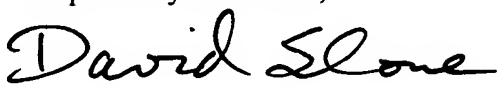
Accordingly, claims 16- 19, 27, and 28 are entitled to additional patentable weight.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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